



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,892	03/21/2005	Yoshiyuki Ueno	IPE-051	9982
7590 Kubovcik & Kubovcik The Farragut Building Suite 710 900 17th Street N W Washington, DC 20006				
			EXAMINER SYKES, ALTREV C	
			ART UNIT 4145	PAPER NUMBER
			MAIL DATE 04/16/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/524,892

**Applicant(s)**

UENO ET AL.

**Examiner**

ALTREV C. SYKES

**Art Unit**

4145

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) 19-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/55/02)  
Paper No(s)/Mail Date 20050713, 20051013
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-18, drawn to a modified substrate.

Group II, claim(s) 19-23, drawn to a separation membrane.

Group III, claim(s) 24-26, drawn to a system of a plurality of modified substrates.

Group IV, claim(s) 27-36, drawn to a process of producing modified substrate.

Group V, claim(s) 37-39, drawn to a method of producing a system comprising a plurality of substrates.

2. The inventions listed as Groups I, II, III, IV, and V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

-The special technical feature of Group I is a modified substrate wherein the substrate comprises a plurality of hydrophilic polymers, while said feature is shared by Groups II through V, it does not offer contribution over the prior art because it is disclosed by Kasai et al. (US 4,776,959)

-The special technical feature of Group II is a separation membrane comprising the modified substrate wherein the hydrophilic polymer is bonded on the inner surface of the hollow fiber membrane, said feature is missing from groups I, III, IV, and V.

-The special technical feature of Group III is a separation membrane system comprising a port element, a separation membrane, and a circuit, and at least a part of the port element, the separation membrane, and the circuit comprises the modified substrate, said feature is missing from groups I, III, IV, and V.

-The special technical feature of Group IV is a method for producing a modified substrate wherein the substrate is a separation membrane, said feature is missing from groups I through III, and V.

-The special technical feature of Group V is a method for producing a system comprising a step of irradiating a plurality of substrates with radiation at the same time while the system comprising the plurality of substrates is brought into contact with an aqueous solution containing a hydrophilic polymer and an antioxidant, said feature is missing from groups I, II, III, and IV.

3. During a telephone conversation with John Forrest on March 31, 2008 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-18. Affirmation of this election must be made by applicant in replying to this Office action. Claims 19-39 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.
4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections

of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

#### ***Claim Objections***

7. Claims 1 and 6 are objected to because of the following informalities: It is not understood what ratio is being claimed by applicant in regards to “wherein the soluble hydrophilic polymer ratio is 15 weight percent or less”. For examination purposes at this time, the claim is treated on the merits with the “weight percent” being the polymer concentration in solution by weight.  
  
Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
9. Claims 6 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.  
  
Claim 6 recites the limitation “the surface hydrophilic polymer”. There is insufficient antecedent basis for this limitation in the claim.

Claim 13 recites the limitation "the absorptivity to interleukin-6". There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-5, 7, 9-11, 13-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Kasai et al. (US 4,776,959).

Regarding claim 1, Kasai et al. discloses:

- A modified substrate comprising a hydrophilic polymer, (See Col 2, lines 35-44)
- wherein the soluble hydrophilic polymer ratio is 15 weight percent or less (See Col 3, lines 11-15)
- and the number of adhered human blood platelets is  $10/4.3 \times 10^3 \mu\text{m}^2$  or less. (See Col 2, lines 35-44, wherein the number of adhered human blood platelets is zero.)

Regarding claim 2 and 4, as the structure and composition of Kasai et al. has been shown to be similar to that of the structure and composition as claimed by Applicant, it is presumed that the prior art can do whatever is claimed since the similarity is substantial. As such, it is noted that the modified substrate of Kasai et al. is also capable of being

obtained by irradiating with radiation while the substrate is brought into contact with an aqueous solution of the hydrophilic polymer and even further with an antioxidant.

Regarding claim 3 and 5, Kasai teaches the claimed invention above. While the reference does not explicitly disclose the modified substrate wherein in the aqueous solution of the hydrophilic polymer, the maximum increasing value of ultraviolet absorption value in the wavelength range of 260 to 300 nm, the increase being caused by irradiating with radiation, is 1 or less, it is reasonable to presume that the maximum increasing value is inherent to Kasai. Support for said presumption is found in the use of like materials and/or like methods which would result in the claimed property. In the instant case, Kasai et al. discloses a modified substrate comprising a hydrophilic polymer which is capable of being made by irradiating with radiation as set forth above. Additionally, the maximum increasing value as claimed is 1 or less wherein less is understood to encompass zero. The burden is upon the Applicant to prove otherwise. *In re Fitzgerald* 205 USPQ 594. In addition, the presently claimed properties would inherently have been present once the Kasai et al. substrate is provided. Note *In re Best*, 195 USPQ at 433, footnote 4 (CCPA 1977).

Regarding claim 7 and 9, Kasai et al. further discloses a modified substrate wherein:

- the substrate comprises a plurality of hydrophilic polymers. (See polymethyl methacrylate Col 6, lines 24-37)
- the substrate comprises an anionic hydrophilic polymer and a nonionic hydrophilic polymer. (See Col 5, lines 9-23)



Regarding claim 10, Kasai teaches the claimed invention above. While the reference does not explicitly disclose the modified substrate wherein in the amount of dissolution of the hydrophilic polymer is  $0.5 \text{ mg/m}^2$  or less, it is reasonable to presume that the amount of dissolution is inherent to Kasai. Support for said presumption is found in the use of like materials and/or like methods which would result in the claimed property. In the instant case, Kasai et al. discloses a modified substrate comprising a hydrophilic polymer which excels in properties such as resistance to heat and resistance to chemicals. (See Col 3, lines 40-46) Kasai et al. also discloses that the porous membrane encompasses a hydrophilic polymer in a solvent exhibiting a satisfactory ability to dissolve the hydrophilic polymer and possessing high stability and a high wetting property with respect to the hydrophobic polymer. (See Col 4, lines 25-32) Additionally, the amount of dissolution as claimed is  $0.5 \text{ mg/m}^2$  or less wherein less is understood to encompass zero. The burden is upon the Applicant to prove otherwise. *In re Fitzgerald* 205 USPQ 594. In addition, the presently claimed properties would inherently have been present once the Kasai et al. substrate is provided. Note *In re Best*, 195 USPQ at 433, footnote 4 (CCPA 1977).

Regarding claims 11, Kasai et al. further discloses a modified substrate wherein:

- the hydrophilic polymer is a polyalkylene glycol or polyvinylpyrrolidone.  
(See Col 5, lines 6-23)

Regarding claim 13, Kasai teaches the claimed invention above. While the reference does not explicitly disclose the modified substrate wherein in the adsorptivity to interleukin-6 is at least  $0.1 \text{ ng/cm}^2$ , it is reasonable to presume that the adsorptivity to

interleuking-6 is inherent to Kasai. Support for said presumption is found in the use of like materials and/or like methods which would result in the claimed property. In the instant case, Kasai et al. discloses a modified substrate similar in composition to that of the applicant. Furthermore, Kasai et al. discloses that the hydrophilic porous membrane finds utility as a final filter for medicinal liquids and transfusion liquids, pharmaceutical filters, and membranes for artificial organs such as artificial kidney and blood plasma separation. (See Col 6, lines 43-53 and Figure 2) The burden is upon the Applicant to prove otherwise. *In re Fitzgerald* 205 USPQ 594. In addition, the presently claimed properties would inherently have been present once the Kasai et al. substrate is provided. Note *In re Best*, 195 USPQ at 433, footnote 4 (CCPA 1977).

Regarding claim 14, Kasai et al. teaches the claimed invention above. While the reference does not explicitly disclose immobilization density of the polyalkylene glycol is 150 to 3,000 mg/m<sup>2</sup> however the reference does disclose the hydrophilic polymer is a block copolymer of polyethylene glycol. (See Col 5, lines 9-23) It is reasonable to presume that the immobilization density of the polyalkylene glycol is 150 to 3,000 mg/m<sup>2</sup> is inherent to Kasai et al. Support for said presumption is found in the use of like materials and/or like methods (i.e. the choice of hydrophilic polymer and the final use of the product substrate) which would result in the claimed property. The burden is upon the Applicant to prove otherwise. *In re Fitzgerald* 205 USPQ 594. In addition, the presently claimed properties would inherently have been present once the Kasai et al. product is provided. Note *In re Best*, 195 USPQ at 433, footnote 4 (CCPA 1977).

Regarding claims 15-17, Kasai et al. further discloses a modified substrate wherein:

- the substrate comprises a hydrophobic polymer. (See Col 2, lines 35-55)
- the hydrophobic polymer is polymethylmethacrylate. (See polymethyl methacrylate-polyethylene glycol in Col 5, lines 9-23 where polyethylene glycol is hydrophilic)
- the substrate is a medical substrate. (See Col 6, lines 43-50)

*Claim Rejections - 35 USC § 103*

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kasai et al. (US 4,776,959) as applied to claim 1 above in view of Graiver et al. (US 5,429,839)

Regarding claim 6, Kasai et al. discloses all of the claim limitations as set forth above but the reference does not disclose the modified substrate wherein the surface hydrophilic polymer ratio is at least 20 weight percent.

Graiver et al. discloses an aqueous coating composition for solid substrates formed from hydrophobic polymers, said composition comprising a solubilized hydrophilic organic polymer. (See Col 4, lines 9-28). Polyvinyl alcohol is a preferred hydrophilic polymer based on the cost and availability of this material. (See Col 4, lines

59-60) The useful upper limit for the concentration of polyvinyl alcohol is determined at least in part by the viscosity of the solution and the capabilities of the equipment used to prepare the solution and coat it on the substrate. (See Col 5, lines 35-38) Using the preferred molecular weight range of from 80,000 to 115,000 the upper limit of polymer concentration appears to be 20 weight percent. (See Col 5, lines 39-41)

As Kasai et al. discloses a hydrophilic porous membrane which is obtained by imparting hydrophilicity uniformly to the surface of a hydrophobic porous membrane and Graiver et al. discloses a preformed hydrophilic polymer grafted onto the surface of a hydrophobic polymer substrate, the art is analogous. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use polyvinyl alcohol as taught by Graiver et al. as the hydrophilic polymer on the surface of the substrate as taught by Kasai et al. for the added benefit of being able to use the substrate in a medical device without having to reproducibly balance the competing homopolymerization and grafting reactions. (See Col 3, lines 31-40)

14. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kasai et al. (US 4,776,959) as applied to claim 7 above in view of Nagatomo et al. (US 5,023,052).

Regarding claim 8, Kasai et al. discloses all of the claim limitations as set forth above but the reference does not disclose the substrate comprises a cationic hydrophilic polymer and a nonionic hydrophilic polymer or the substrate comprises an anionic hydrophilic polymer and a nonionic hydrophilic polymer. However, Kasai does disclose

the hydrophilic polymer is a vinyl alcohol-vinyl acetate copolymer, poly(2-hydroxyethyl methacrylate), a random or block copolymer of vinyl pyrrolidone such as vinyl acetate-vinyl pyrrolidone copolymer, a block copolymer of polyethylene glycol such as polymethyl methacrylate-polyethylene glycol block copolymer, a segmented polyurethane having polyethylene glycol as a soft segment thereof, or a block or random polyamino acid combining a hydrophilic amino acid with a hydrophobic amino acid and the hydrophobic polymer is polyvinylidene fluoride. (See Col 5, lines 9-23 wherein a random or block copolymer of vinyl pyrrolidone such as vinyl acetate-vinyl pyrrolidone copolymer is nonionic) Kasai et al. also discloses that the membrane produced can be used for blood plasma separation. (See Col 6, lines 43-50)

Nagatomo et al. discloses an element for dry chemical analyses useful for quantitative determination of a specific substance in body fluids, such as blood. (See Col 1, lines 5-7) The analytical element may have various layer structures, for example a layer structure (1) comprising a support having provided thereon the first non-fibrous porous layer, the second non-fibrous porous layer. (See Col 5, lines 25-30) Additionally, Nagatomo et al. discloses a layer structure (2) comprising a support having provided thereon an adhesive layer (or water absorbing layer). (See Col 5, lines 30-35) A third structure taught by Nagatomo et al. comprises a support having provided thereon a detecting layer which generally comprises a hydrophilic polymer and may contain a mordant, for example a cationic polymer mordant. (See Col 48-58)

As Kasai et al. discloses a hydrophilic porous membrane which can be used for filters of medicinal liquids and blood plasma separation and Nagatomo et al. discloses an

analytical element in which the blood cells in whole blood can be separated from blood plasma, the art is analogous. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to provide a detecting layer having a cationic polymer as taught by Nagatomo et al. on the substrate of Kasai et al. having a nonionic polymer thereon for the added benefit of being able to produce a substrate capable of being used to analyze a specific component in whole blood, thereby giving a highly precise result irrespective of the hematocrit value of the blood. (See Col 2, lines 54-61)

15. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kasai et al. (US 4,776,959) as applied to claim 1 above in view of Ricketts et al. (US 2,715,091).

Regarding claim 12, Kasai et al. discloses all of the claim limitations as set forth above but the reference does not disclose the hydrophilic polymer is a polymer derived from the living body.

Ricketts et al. discloses anticoagulants for use with blood and plasma which are non-toxic and may be readily prepared on a large scale. (See Col 1, lines 18-21) Ricketts et al. also discloses a water soluble salt of dextran sulphate as an anticoagulant. (See Title and Col 4, lines 52-57) The anticoagulant may be successfully employed after blood has been shed "in vitro" or used within the body "in vivo". (See Col 1, lines 25-26 and Col 2, lines 9-10)

As Kasai et al. discloses a hydrophilic porous membrane which can be used as a final filter for transfusion and Ricketts et al. also discloses the manufacture of anticoagulants for use with blood and plasma, the art is analogous. Therefore, it would

have been obvious to one of ordinary skill in the art at the time of the invention to utilize the anticoagulant of Ricketts et al. as the hydrophilic polymer on the substrate of Kasai et al. in order to produce a final membrane that would prevent blood from clotting while the membrane was being used as a final filter for a transfusion.

16. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kawaguchi et al. (US 5,658,466) in view of Aoyagi et al. (US 4,609,464).

Regarding claim 18, Kawaguchi et al. discloses:

- A modified substrate (See dialyzing membrane Col 3, lines 4)  
obtainable by irradiating with radiation (See  $\gamma$ -ray irradiation Col 2, lines 39-44)  
while the substrate is brought into contact with an aqueous solution  
containing a hydrophilic polymer (See polymeric material in Col 3, lines 23-41 and dihydric aliphatic alcohols in Col 3, lines 63-67)

Kawaguchi et al. discloses all of the claim limitations as set forth above but the reference does not disclose an aqueous solution containing a hydrophilic polymer and an antioxidant.

Aoyagi et al. discloses a hollow fiber for use in dialysis and an artificial kidney utilizing the hollow fiber. (See Col 1, lines 6-11) Additionally, Aoyagi et al. discloses the hollow fibers are invariably manufactured by extruding the cuprammonium cellulose spinning dope into a gaseous atmosphere, allowing the extruded tube of spinning dope to fall under its own weight, and thereafter submerging the tube under a coagulating

solution thereby coagulating and regenerating the spinning dope. (See Col 2, lines 1-4)

Additionally, the hollow fiber is a dialytic hollow fiber of cuprammonium cellulose having a continuously perforated hollow core throughout the entire length thereof. (See Col 5, lines 58-61) The cuprammonium solution is prepared by mixing an aqueous ammonium copper solution with aqua ammonia, an aqueous basic copper sulfate solution and water. (See Col 7, lines 39-43) This aqueous ammonium copper solution is mixed with an antioxidant (such as, for example, sodium sulfite) and then with cellulose, as the basic material, and the resultant mixture is stirred to ensure solution. (See Col 7, lines 43-46)

As Kawaguchi et al. discloses a blood dialyzer (artificial kidney) having dialyzing membranes in the form of hollow fibers and Aoyagi et al. also discloses an artificial kidney having dialytic hollow fibers, the art is analogous. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to utilize the antioxidant in the production of the hollow fibers as taught by Aoyagi et al. in the production of the artificial kidney of Kawaguchi et al. in order to provide an artificial kidney system having excellent dialytic effect. (See Col 2, lines 58-61)

Absent a showing to the contrary, it is the examiner's position that the article of the applied prior art is identical to or only slightly different than the claimed article. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is



unpatentable even though the prior product was made by a different process. *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985). The burden has been shifted to the applicant to show unobvious difference between the claimed product and the prior art product. *In re Marosi*, 218 USPQ 289 (Fed. Cir. 1983). The applied prior art either anticipated or strongly suggested the claimed subject matter. It is noted that if the applicant intends to rely on Examples in the specification or in a submitted declaration to show non-obviousness, the applicant should clearly state how the Examples of the present invention are commensurate in scope with the claims and how the Comparative Examples are commensurate in scope with the applied prior art. In the instant case, Kawaguchi et al. discloses a  $\gamma$ -ray sterilization procedure of packing the dialyzer with the aqueous solution of the dihydric aliphatic alcohol or impregnating the dialyzing membranes in the dialyzer with the aqueous solution, optionally sealing the dialyzer, and applying  $\gamma$ -ray irradiation to the dialyzer. (See Col 5, lines 30-34) Alternatively, the above-mentioned dialyzer can be placed in a sterilizing bag and the  $\gamma$ -ray irradiation can be applied to the dialyzer through the bag. (See Col 5, lines 35-37)

### ***Conclusion***

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALTREV C. SYKES whose telephone number is (571)270-3162. The examiner can normally be reached on Monday-Thursday, 7:30AM-5PM EST, alt Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Basia Ridley can be reached on 571-272-1453. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ACS/  
4/2/08

/Basia Ridley/  
Supervisory Patent Examiner, Art Unit 4145